**Application Form for General Consultation**

Please fill in the following fields with blue shading (\* Required): Fill in that item (\*: mandatory).

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| --- | --- | --- | --- | --- |
|  |  |  | Control No. number | Click or tap here to enter the text. |
| (1) | Application date\* | Click or tap here to enter the text. |
| (2) | Category of consultation\* | [ ]  Pharmaceutical Products[ ]  Medical Devices (Including in vitro diagnostics) | [ ]  Regenerative medicine products (Cell and gene therapy products)[ ]  Others (Overall general regulatory system in Japan, etc.) |
| (3) | Sub-category\* | Select the item. |
| (4) | Applicant name\* | Click or tap here to enter the text. |
|  | Contact Information | Company name\* | Click or tap here to enter the text. |
| (5) | Affiliation\* | Click or tap here to enter the text. |
| E-mail address\* | Click or tap here to enter the text. |
|  | Phone number\* | Click or tap here to enter the text. |
| (6) | List of attendees(Name/Department/Position) \* | Click or tap here to enter the text. |
| (7) | Matters for Consultation\* | Background:Click or tap here to enter the text.Consultation matters (Questions):Click or tap here to enter the text. |
| (8) | List of consultation materials attached to this application form (If applicable) | Click or tap here to enter the text. |
| (9) | Preferred meeting format\* | [ ]  Onsite (PMDA Washington D.C. Office)[ ]  Online (Microsoft Teams hosted by applicants) |
| (10) | Preferred date and time of meeting\*(Enter at least 3 options) | Click or tap here to enter the text. |
| (11) | Additional Remarks | Click or tap here to enter the text. |

Notes:

1 Please fill in the field with blue shading. Do not fill in the control number field.

2 The procedures for filling out the application form are as follows.

(2) Category of consultation

Select the appropriate item for the product to be consulted.

(3) Sub-category

Select the sub-category of consultation from the list.

(6) List of attendees

If some of the attendees wish to participate on-site and others wish to participate on-line, please circle the names of the on-site attendees.

(7) Matters for Consultation

Summarize the background that led to the submission of this application, and briefly describe the issues and concerns on development (e.g., using bullet points). If there is more than one consultation matter (question), enter each of them separately. Please note that consultation matters (questions) other than those described in this field cannot be answered.

(8) List of consultation materials attached to this application form

If you wish to submit materials related to the consultation matters (questions), enter the file title and file size as a list of materials using bullet points. Please conspicuously indicate “Confidential” in case confidential materials are included.

(9) Preferred meeting format

Check the preferred format. If some of the attendees wish to participate in person and others wish to participate on-line, check both formats. It is possible to conduct online meetings through Microsoft-Teams arranged and hosted by the applicants at their sole responsibility.

(10) Preferred date(s) of meeting

Enter at least 3 options for the date and time for consultation.

(11) Additional Remarks

If you previously had our consultation with respect to product for which you are requesting for a second or additional consultation, please enter the date(s) of the prior consultation(s).

In addition, please enter any salient additional information.